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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,974	10/26/2001	Gabriel Nunez	UM-06646	3481

7590 12/02/2002

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 12/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/002,974	NUNEZ ET AL.
	Examiner	Art Unit
	Jeanine A Goldberg	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 April 2002.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-33 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .                    6) Other: \_\_\_\_\_ .

## DETAILED ACTION

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-12, 24-33 drawn to a method of identifying subjects at risk of developing Crohn's disease by providing a nucleic acid sample from a subject and detecting the presence or absence of one or more variations, and a computer implemented method which requires sampling nucleic acid and detecting the presence or absence of one or more variations classified in class 435, subclass 6 and 702/27. This group is subject to further restriction below.
  - II. Claims 13-14, drawn to kits comprising a detection assay and instructions and a probe selected from SEQ ID NO: 70-83, classified in class 536, subclass 24.31. This group is subject to further restriction below.
  - III. Claims 15-20, drawn to nucleic acids encoding polypeptides (SEQ ID NO: 55, 57, 59, 61, 63, 65, 67, 69, 85, 87, 89, 54, 56, 58, 60, 62, 64, 66, 68, 84, 86, 88), host cells and vectors, classified in class 536, subclass 23.1. 435/320.1. 435/325, for example. This group is subject to further restriction below.
  - IV. Claim 21, 23, drawn to a computer readable medium encoding a representation of the nucleic acid sequences or polypeptide, classified in class 707, subclass 100.
  - V. Claim 22, drawn to a polypeptide, classified in class 530, subclass 350.

2. The inventions are distinct, each from the other because of the following reasons:

- A) Group I and (IV, V) are patentable distinct inventions because the computer readable medium and polypeptides of Group IV, V is not relied upon in the method of Group I. Instead Group I uses nucleic acids for detection. Therefore, the inventions are novel and unobvious over one another.
- B) Inventions I and (II, III) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group II and III may be used in a materially different method. For example the nucleic acids may be used in purification methods, aptamer screening methods, hybridization assays, antisense methods, for example.
- C) Group II and III are patentable distinct nucleic acids. The nucleic acids are drawn to the wild type (SEQ ID NO: 1) and 33, 54, 56, 58, 60, 62, 64, 66, 68, 84, 86, 88 (variant alleles)(page 47 of specification). Table 1, page 64 of the specification teaches the numerous different variant sequences and the corresponding SEQ ID NO:. Each sequence represents a patentably distinct nucleic acid.
- D) The inventions of Groups II, III, IV and V are patentably distinct products because the DNA of Group III and the protein of Group V have different structures, properties and functions. The DNA of Group I is composed of nucleotides linked in

phosphodiester bonds and arranged in space as a double helix. The DNA can function not only for the expression of the protein but also as a probe in a nucleic acid hybridization assay and in a nucleic acid amplification assay, for example. In contrast, the polypeptide of Group V is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The polypeptide can function not only as a receptor but also for the generation of polyclonal and monoclonal antibodies and for the affinity purification of those antibodies or of ligands for the receptor. The computer readable medium of Group IV does not contain any chemical structure.

**Restriction Requirement Applicable to All Groups:**

3. The claims are directed to multiple sequences which are related to several polymorphic variants of the Nod2 gene. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications. A restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequences (See MPEP 803.04).

The claims contains 12 individual, independent and distinct nucleotide sequences in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. 121 as outlined in 1192 O.G. 68 (November 19, 1996).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Applicant is required to select one of the individual sequences for examination. The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers). Applicants may select a single polymorphism and the probes and primers which are specific for the selected polymorphic variant.

Should applicant traverse on the ground that the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

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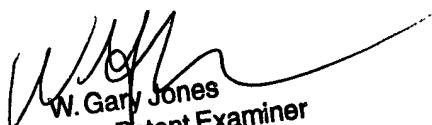
or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg  
November 27, 2002



W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600